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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,989	03/20/2000	Jean Marie Vogel	9676-292	6000

20582 7590 11/26/2003

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EXAMINER	
WELLS, LAUREN Q	

ART UNIT	PAPER NUMBER
1617	27

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/528,989	VOGEL ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,11-20 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 7, 8, 11-20, 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Inventorship

The request to correct the inventorship of this non-provisional application under 37 CFR 1.48(a) is deficient because:

> The statement of facts by an inventor or inventors to be added or deleted does not explicitly state that the inventorship error occurred without deceptive intent on his or her part or cannot be construed to so state.

While the "Request for Correction of Inventorship" filed on 8/11/03, Paper # 25, states that there is "A statement by Mr Thomas", no statement by Mr Thomas was actually filed.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

11/25/05

DETAILED ACTION

Claims 1-4, 7-8, 11-20 and 52 are pending. The Amendment filed 8/11/03, Paper No. 24, amended claim 12, added claim 52, and cancelled claims 5, 6, 9, 10, 21-51.

Petition to Correct Inventorship

The request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because:

> The statement of facts by an inventor or inventors to be added or deleted does not explicitly state that the inventorship error occurred without deceptive intent on his or her part or cannot be construed to so state.

While the "Request for Correction of Inventorship" filed on 8/11/03, Paper No. 25, states that there is "A statement by Mr. Thomas", no statement by Mr. Thomas was actually filed.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 8/11/03 (Paper No. 24) to the rejection of claims 1-4, 7-8, 11-20 made by the Examiner under 35 USC 103 and the judicially created doctrine of double patenting have been fully considered and deemed not persuasive.

The Applicant's amendment to the claims filed 8/11/03 (Paper No. 24) is sufficient-in-part to overcome the 35 USC 112 rejections in the previous Office Action. See below for details.

Double Patenting Rejection Maintained

The rejection of claims 1-4, 7-8, 11-20 under over the judicially created doctrine of double patenting over claims 1-7, 7-9, 12-19 of US Patent No. 6,436,424 and over claims 1-4, 7-8, 11-20 of copending Application No. 10/222,8919 is MAINTAINED for the reasons set forth in the Office Action mailed 2/12/03, Paper No. 22, and those found below.

Applicant argues, "The claims of the '424 patent and the '819 application are directed to an injectable composition, for dermal augmentation, wherein the composition is injectable through needles of about 30 gauge or smaller. On the contrary, the present claims recite an injectable composition for tissue bulking, wherein the composition is injectable through needles of 18-26 gauge". This argument is not persuasive. First, the Examiner respectfully points out that the intended use of the composition is not given patentable weight. Second, the Examiner respectfully points out that "less than about 30 gauge" encompasses a range of 18-26 gauge, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

112 Rejection Maintained

The rejection of claim 20 under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed 2/12/03, Paper No. 22, and those found below.

Regarding the phrase "capable of", Applicant argues, "the term is clearly defined in the specification, e.g., at page 15, line 29 to page 16, line 5, and that a person of ordinary skill in the art would know exactly what the term fairly conveys in the context in which it is used". This argument is not persuasive. The Examiner respectfully points out that page 15, line 29-page 16, line 5, contains no definition of the phrase "capable of".

Applicant argues that the phrase "capable of" is a proper functional limitation and that MPEP 2173,05(g) specifically states that the term "capable of" has been held definite and precisely defined in the claimed invention. This argument is not persuasive. It is respectfully pointed out that MPEP 2173.05(g) does not state that the term "capable of" has been held

definite, but states that in a claim that was directed to a kit of component parts capable of being assembled. Thus, this citation does not make reference to a claim that recites the phrase "capable of". This phrase is vague and indefinite, as it is confusing and conveys no limitations to the instant claims, because while something is "capable of", it does not mean that it performs such a function. The Examiner respectfully suggests that Applicant delete the phrase "capable of being" to overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7-8, 11-20 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (WO 99/44643) in view of Hubbard (5,922,025).

The instant invention is directed toward a composition comprising biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres and a biocompatible carrier.

Vogel et al. teach implantable particles comprising cationic, hydrophilic microparticles and a cell adhesion promoter for tissue bulking and the treatment of gastroesophageal reflux disease, urinary incontinence, and skin wrinkles. The microparticles are pre-coated with autologous cells, such as muscle and fat cells. Hydrophilic copolymers are those of the acrylic family, such as polyacrylamides, polyacrylates, polyallyl compounds, and polyvinyl compounds. It is disclosed that all of these polymers are crosslinked. Spherical microparticles are the

preferred shape and 10-1000 micrometers is the preferred diameter. The microparticles are stable in suspension and can be injected with different liquids. Contrast agents, such as barium or iodine salts, can be added to the microparticles. The microparticles can be injected with anti-inflammatory drugs to decrease local inflammation. The microparticles can be added to aqueous or hydro-organic solutions. Exemplified are compositions comprising 90grams of methylolacrylamide, 2 grams of methacrylamidopropyl-trimethyl-ammonium-chloride hydrochloride and 10 grams of N,N'-methylene-bis acrylamide (cross-linker) added to 10mg/ml anti-inflammatory drug solution in sterile physiological saline. The reference lacks an exemplification and preferred percent weight ranges. See pg. 7, line 25-pg. 14, line 17; pg. 20, line 9-line 32; pg. 22, line 10-pg. 30, line 30.

Hubbard teaches soft tissue augmentation material comprised of spherical particles. The particles are disclosed as ranging in size from 35 to 150 microns and is being injected through an 18 gauge syringe. See Col. 5, lines 1-45.

The Examiner respectfully points out that the phrase, "wherein the composition is injectable through needles of about 18 to 26 gauge" is a future intended use and therefore not afforded patentable weight. However, as evidenced by Hubbard, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Vogel as injectable through an 18 gauge syringe because a)Hubbard and Vogel both teach microspheres for tissue augmentation, and b) the range of the size of microspheres taught by Vogel overlaps the range taught by Hubbard, wherein the size of the microspheres determines the syringe gauge size; thus, one of skill in the art would be motivated to inject the microspheres

of Vogel through an 18 gauge syringe because Hubbard teaches that microspheres within the particle size range of Vogel can be administered via an 18 gauge syringe.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the percent weight ranges of cross-linkers, microspheres, and biocompatible carriers of Vogel as that recited in the instant invention because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

NOTE: The phrases, "for tissue bulking in a mammal" and "wherein said composition is injectable through needles of about 18 to 26 gauge and wherein said microspheres swell to a predetermined size after injection within the non-dermal tissue of said mammal" in claim 1 are recitations of intended use. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

It is furthermore respectfully noted that since the above rejection teaches the same microspheres as that of the instant invention, the microspheres of the rejection must share the same swell sizes.

Response to 35 USC 103 Arguments

Applicant argues, "Vogel should be removed. . .because the inventive entity in Vogel and the present application is the same". This argument is not persuasive, as Applicant's Petition to Correct Inventorship is deficient, as pointed out above.

Applicant's arguments against Hubbard are not persuasive, as Hubbard is merely relied upon to teach that particles in a size range of 35-150 microns are known to be injected through an 18 gauge syringe.

Applicant's arguments against the "needle gauge" recitation are not persuasive, as the Examiner has addressed these limitations in the previous Office Action.

Applicant's arguments against the "swell" recitation are not persuasive, as the Examiner addressed this limitation in the previous Office Action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

THEODORE J. CRIARES
PRIMARY EXAMINER
GROUP 1200